



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2013-C-1008]

Wm. Wrigley Jr. Company; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by the Wm. Wrigley Jr. Company, proposing that the color additive regulations be amended to expand the use of synthetic iron oxide to include soft and hard candy, mints, and chewing gum. The petition also proposes to lower the specification limit for lead in synthetic iron oxide for human food use.

DATES: The color additive petition was filed on July 16, 2013.

FOR FURTHER INFORMATION CONTACT: Laura A. Dye, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1275.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), notice is given that we have filed a color additive petition (CAP 3C0298) submitted by the Wm. Wrigley Jr. Company, c/o Exponent Inc., 1150 Connecticut Ave., NW., suite 1100, Washington, DC 20036. The petition proposes to amend the color additive regulations in § 73.200 Synthetic iron oxide (21 CFR 73.200) to expand the use of synthetic iron oxide to include soft and hard candy, mints, and chewing gum. The petition also

proposes to lower the specification limit for lead in synthetic iron oxide for human food use from 10 milligrams per kilogram (mg/kg; 10 parts per million (ppm)) to 5 mg/kg (5 ppm).

We have determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: September 11, 2013.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

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